

Fin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application No. 10/801,118

Art Unit: 1642

Inventors: Jui H. Wang; Hongtao Liao; Long Shen; and
Xiaolan Chen

Examiner: Not Assigned

Filed: March 15, 2004

Title: **Poly-DNP-siRNA**

Customer No. 23910

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited in the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Nov. 9, 2004.

D. Benjamin Borson (Attorney Signature)
D. Benjamin Borson, Ph.D.
Registration No. 42,349

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

It is requested that the information identified in this statement be considered by the Examiner and made of record in the above-identified application. This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56. If this is a continuation, divisional or continuation-in-part application, it is understood that the Examiner will consider all information which was considered by the Office in a parent application. MPEP §609. Such information therefore is not listed herein unless it is desired that the information be printed on a patent issuing from the subject application.

Enclosed with this statement are the following:

☒ Form PTO-1449. The Examiner is requested to initial the form and return it to the undersigned in accordance with M.P.E.P. §609.

☐ A copy of the International Search Report.

☒ The present application is being/was filed after June 30, 2003. In accordance with the pre-official gazette waiver of 37 CFR 1.98 (a)(2)(i) posted at: pac/dapp/opla/preognotice/idswouscopies.htm, copies of cited U.S. patents and publications are not enclosed. However, copies of cited foreign

patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98(a)(2), as still required, except for those items designated by an asterisk (*), which were previously submitted by the applicant in a parent application, from which benefit under 35 U.S.C. §120 is claimed, with an *Information Disclosure Statement* submitted in the parent application which complies with the September 8, 2000 or subsequent revision of 37 C.F.R. §1.98(a-c), as allowed under 37 C.F.R. §1.98(d)(1).

— The present application was filed prior to June 30, 2003. A copy of each cited document as required by 37 C.F.R. §1.98 is enclosed, except for those items designated by an asterisk (*), which were previously submitted by the applicant in a parent application, from which benefit under 35 U.S.C. §120 is claimed, with an *Information Disclosure Statement* submitted in the parent application which complies with the September 8, 2000 or subsequent revision of 37 C.F.R. §1.98(a-c), as allowed under 37 C.F.R. §1.98(d)(1).

— If any of the cited/submitted documents is in a foreign language, a concise explanation of relevance is provided pursuant to 37 C.F.R. §1.98(a)(3)(i). For foreign language documents cited in a search report by a foreign patent office, the requirement for a concise explanation of relevance is satisfied by the submission herewith of an English language version of the search report. MPEP §609A(3). If a written English-language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in §1.56(c), a copy of the translation accompanies this statement, 37 C.F.R. §1.98(a)(3)(ii), and satisfies the requirement for a concise explanation of relevance, MPEP §609A(3).

✓ ***PTA Statement under 37 C.F.R. §1.704(d).*** Each item of information contained in the *Information Disclosure Statement* was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the *Information Disclosure Statement*.

This statement should be considered because:

✓ **37 C.F.R. §1.97(b).** This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:

- (1) It is being filed within three months of the filing date of an application other than a continued prosecution application under § 1.53(d);
-- OR --
- (2) It is being filed within 3 months of entry of a national stage;
-- OR --
- (3) It is being filed before the mailing date of the first Office Action on the merits,
-- OR --
- (4) It is being filed before the mailing date of the first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

— **37 C.F.R. §1.97(c).** Although it may not qualify under subsection (b), this statement qualifies under 37 C.F.R. §1.97, subsection (c) because:

- (1) It is being filed before the mailing date of a FINAL Office Action, a Notice of Allowance, or an action that otherwise closes prosecution in the subject application, whichever occurs first.

-- AND (check at least one of the following) --

- ___ (1) It is accompanied by a STATEMENT as set forth in 37 C.F.R. §1.97(e).
-- OR --
___ (2) It is accompanied by the \$180 fee set forth in 37 C.F.R. §1.17(p).

___ **37 C.F.R. §1.97(d).** Although it may not qualify under subsection (b) or (c), this statement qualifies under 37 C.F.R. §1.97, subsection (d) because:

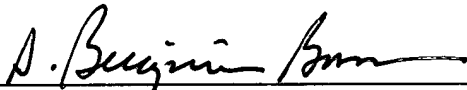
- (1) It is being filed on or before payment of the Issue Fee;
-- AND --
(2) It is accompanied by a STATEMENT as set forth in 37 C.F.R. §1.97(e);
-- AND --
(3) It is accompanied by the \$180 fee set forth in 37 C.F.R. §1.17(p).

✓ **Fee Authorization.** The Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Account No. 06-1325. A duplicate copy of this authorization is enclosed.

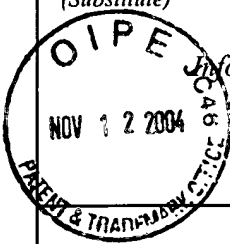
Respectfully submitted,

FLIESLER MEYER LLP

Date: NOV. 9, 2004

By: 
D. Benjamin Borson, Ph.D.
Registration No. 42,349

FLIESLER MEYER LLP
Four Embarcadero Center, Fourth Floor
San Francisco, CA 94111-4156
Telephone (415) 362-3800
Facsimile (415) 362-2928

Form PTO-1449 (Substitute)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Attorney Docket Number DNPP-2007US0 DBB		Serial/Patent Number 10/801,118	
 <p>Information Disclosure Statement BY APPLICANT (Use several sheets if necessary)</p>				Applicant/Patent Owner Jui H. Wang et al. Assigned to DNP Pharmaceuticals, Inc.			
				Filing/Issue Date March 15, 2003		Group Art Unit 1642	
U.S. PATENTS							
Examiner Initial		Patent Number	Issue Date	First Named Inventor	Class	Subclass	Filing Date
	A	5,514,577	5/7/96	Draper et al.	435	238	3/12/93
	B	5,466,786	11/14/95	Buhr et al.	536	26.26	5/10/94
	C	5,496,546	3/5/96	Wang et al.	424	78.36	2/23/94
	D	5,858,988	1/12/99	Jui H. Wang	514	44	2/22/96
	E	6,291,438	9/18/01	Jui H. Wang	514	44	10/6/98
U.S. PATENT PUBLICATIONS							
Examiner Initial		Patent Application Publication Number	Publication Date	Applicant			
PENDING U.S. PATENT APPLICATIONS							
Examiner Initial		Application Number	Filing Date	First Named Inventor	Petition to Expunge? Yes No		
FOREIGN PATENT DOCUMENTS							
Examiner Initial		Document Number	Publication Date	Country	Class	Subclass	Trans- lation Yes No
	A	WO 01/75164	10/11/01	PCT	C12Q	1/68	X
	B	WO 92/20697	11/26/92	PCT	C07H	21/00	
OTHER DOCUMENTS (Include author (if any), title, publisher and place of publication, date and pertinent pages)							
	A	Amarzguioui, Mohammed; Holen; Torgeir; Bable, Eshrat; and Prydz, Hans, "Tolerance for Mutations and Chemical Modifications in a siRNA," <u>Nucleic Acid Research</u> , 2003, Vol. 31, No. 2, pp. 589-595.					

OTHER DOCUMENTS (Include author (if any), title, publisher and place of publication, date and pertinent pages)		
B	Ashun, Mary Apea; Hu,Yin; Kang, Insug; and Li, Chih C.; and Wang, Jui.H., "Inhibition of Murine Leukemia Virus with Poly-2'-O-(2, 4-dinitrophenyl) Poly[A]., <u>Anitmicrobial Agents and Chemotherapy</u> , October 1996, Vol. 40, No. 10, pp. 2311-2317.	
C	Chen, Xiaolan; Shen; Long; and Wang, Jui.H., "Poly-2'-DNP-RNAs with Enhanced Efficacy for Inhibiting Cancer Cell Growth," <u>Oligonucleotides</u> , Bioenergetics Laboratory, Natural Sciences Complex, University at Buffalo, NY 14260-3000, 2004, pp.14:90-99.	
D	Czauderna, Frank; Fechtner, Melanie; Dames, Sibylle; Hüseyin, Aygün; Klippel, Anke; Pronk, Gijsbertus J.; Giese, Klaus; and Kaufmann, Jörg, "Structural Variations and Stabilising Modifications of Synthetic siRNAs in Mammalian Cells," <u>Nucleic Acids Research</u> , 2003, Vol. 31, No. 11, pp. 2705-2716.	
E	Elbashir, Sayda M.; Harborth, Jens; Lendeckel, Winifried; YalcIn, Abdullah; Weber, Klaus; and Tuschl, Thomas, "Duplexes of 21-Nucelotide RNAs Mediate RNA Interference in Mammalian Cell Culture," <u>Nature</u> , May 24, 2001, Vol. 411, pp. 494-498.	
F	Fire, Andrew; Xu, SiQun; Montgomery, Mary K.; Kostas, Steven A.; Driver, Samuel E.; and Mello, Craig C., "Potent and Specific Genetic Interference by Double-Stranded RNA in <i>Caenorhabditis elegans</i> ," <u>Nature</u> , February 19, 1998, Vol. 391, pp.306-811.	
G	Giles, Richard V. and Tidd, David M., "Increased Specificity for Antisense Oligodeoxynucleotide Targeting of RNA Cleavage by Rnase H using Chimeric Methylphosphonodiester/Phosphodiester Structures, <u>Nucleic Acids Research</u> , 1992 Oxford University Press, January 20, 1992, Oxford University Press, Vol. 20, No. 4, pp. 763-770.	
H	Grünweller, Arnold; Wyszko, Eliza; Bieber, Birgit; Jahnel, Ricarda; Erdmann, Volker A.; and Kurreck, Jens, "Comparison of Different Antisense Strategies in Mammalian Cells Using Locked Nucleic Acids, 2'-O-Methyl RNA, Phosphorothioates and Small Interfering RNA," <u>Nucleic Acids Research</u> , 2003, Vol. 31, No. 12, pp. 3185-3193.	
I	Hamilton, Andrew J. and Baulcombe, David C., "A Species of Small Antisense RNA in Posttranscriptional Gene Silencing in Plants," <u>Science</u> , October 29, 1999, Vol. 286, pp. 950-952.	
J	Hannon, Gregory J., "RNA Interference," <u>Nature</u> , July 11, 2002, Vol. 418, pp. 244-251.	
K	Harborth, Jens; Elbashir, Sayda M.; Vandenburgh, Kim; Manninga, Heiko; Scaringe, Stephen A.; Weber, Klaus; and Tuschl, Thomas, "Sequence, Chemical, and Structural Variation of Small Interfering RNAs and Short Hairpin RNAs and the Effect on Mammalian Gene Silencing," <u>Antisense and Nucleic Acid Drug Development</u> , 2003, pp. 83-105.	
L	Holen, Torgeir; Amarzguioui, Mohammed; Babaie, Eshrat; and Prydz, Hans, "Similar Behaviour of Single-Strand and Double-Strand siRNAs Suggests They Act Through a Common RNAi Pathway," <u>Nucleic Acids Research</u> , 2003, Vol. 31, No. 9, pp. 2401-2407.	
M	Holen, Torgeir; Amarzguioui, Mohammed; Babaie, Eshrat; and Prydz, Hans, "Positional Effects of Short Interfering RNAs Targeting the Human Coagulation Trigger Tissue Factor," <u>Nucleic Acids Research</u> , 2002, Vol. 30, No. 8, pp. 1757-1766.	
N	Martinez, Javier; Patkanowska; Urlaub, Henning; Lührmann; and Tuschl, Thomas, "Single-Stranded Antisense siRNAs Guide Target RNA Cleavage in RNAi," September 6, 2002, <u>Cell</u> , Department of Cellular Biochemistry, Germany, Vol. 110, pp. 563-574.	
O	Milligan, John F.; Groebe, Duncan R.; Witherell, Gary W.; and Uhlenbeck, Olke C., "Oligoribonucleotide Synthesis Using T7 Polymerase and Synthetic DNA Template," <u>Nucleic Acids Research</u> , 1987, Vol. 15, No. 21, pp. 8783-8798.	

OTHER DOCUMENTS (Include author (if any), title, publisher and place of publication, date and pertinent pages)		
	P	Miyagishi, Makoto; Hayashi, Mariko; and Taira, Kazunari, "Comparison of the Suppressive Effects of Antisense Oligonucleotides and siRNAs Directed Against the Same Targets in Mammalian Cells," <u>Antisense and Nucleic Acid Drug Development</u> , " 2003, Vol. 13, pp. 1-7.
	Q	Pusch, Oliver; Boden, Daniel; Silbermann, Rebecca; Lee, Fred; Tucker, Lynne; and Ramratnam, Bharat, "Nucleotide Sequence Homology Requirements of HIV-1-Specific Short Hairpin RNA," <u>Nucleic Acids Research</u> , " Vol. 31, No. 22, pp. 6444-6449.
	R	Rahman, M. Habibur; Kang, Insug; Waterbury, Raymond G.; Narang, Upvan; Bright, Frank V.; and Wang, Jui H., "Selective Removal of Ribonucleases from Solution with Covalently Anchored Macromolecular Inhibitor," <u>Analytical Chemistry</u> , January 1, 1996, Vol. 68, No. 1, pp. 134-138.
	S	Ru, Kun; Schmitt, Shawn; James, William I.; and Wang, Jui H., "Growth Inhibition and Antimetastatic Effect of Antisense Poly-DNP-RNA on Human Breast Cancer Cells," <u>Oncology Research</u> , " 1999, Vol. 11, pp. 505-512.
	T	Shen, Long; Chen, Xiaolan; and Wang, Jui H., "A High-Efficacy Antisense _{R18} Poly-DNP 21-nt RNA," <u>Antisense and Nucleic Acid Drug Development</u> , "Vol. 13, pp. 67-74.
	U	Zamecnik, Paul C., and Stephenson, Mary L., "Inhibition of Rous Sarcoma Virus Replication and Cell Transformation by a Specific Oligodeoxynucleotide," <u>The John Collins Warren Laboratories of the Huntington Memorial Hospital at Harvard University at the Massachusetts General Hospital</u> , " November 10, 1977, Vol. 75, No. 1, pp. 280-284.
	V	Zamore, Phillip D.; Tuschli, Thomas; Sharp, Phillip A. Sharp; and Bartel, David P., "RNAi: Double-Stranded RNA Directs the ATP-Dependent Cleavage of mRNA at 21 to 23 Nucleotide Intervals," <u>Cell</u> , March 31, 2000, Vol. 101, pp. 25-33.
	W	Steward, David L., et al., "Influence of 2'O-acetylation On the Antiviral Activity of Polyribonucleotides," <u>Biochim Biophys. Acta</u> , 1972, pp. 262, 227-232.
	X	Chuan, Hua et al., "3'O-(5-Fluoro-2, 4-dinitrophenyl)ADP Ether and ATP Ether," <u>The Journal of Biological Chemistry</u> , " September 15, 1988, Vol. 263, No. 26, pp. 13003-13006.
	Y	Kang Insug, et al., "Design of Structure-based Reverse Transcriptase Inhibitors," <u>The Journal of Biological Chemistry</u> , April 22, 1994, Vol. 269, No. 16, pp. 12024-12031.
	Z	Steward, David L. et al., <u>Chemistry Abstract</u> , 77:1242G.
	AA	William, <u>Chemistry Abstract</u> , 1977, 87(23) pp.177597.
	BB	<u>Chemistry Abstract</u> , 1975, 83:158731.
	CC	E. Lesnik et al., <u>Biochemistry</u> , 1993, 32:7837.8.
	DD	J. Grzybowski et al., <u>Nucleic Acides Research</u> , 1993, 21(8), pp.1705-12.
Examiner		Date Considered